

REMARKS

1. *Status of claims*

After entry of the above amendment, claims 1-6 are withdrawn and claims 7-16 are pending and under consideration.

2. *Support for amendment*

The amendment of claim 11 corrects an inadvertent error; it will be apparent that the original reference to non-existent "claim 19" was a mistyping of "claim 10," given that the numerals "9" and "0" are adjacent on standard computer keyboards. The amendment of claim 13 inserts a space which, as will be apparent, properly belongs in the original text "12wherein." No new matter has been added by this amendment.

3. *Claim objections*

The Examiner objected to claims 11 and 13 for containing informalities. These informalities are corrected by the foregoing amendment and remarked upon under Remarks, ¶ 2, above. Therefore, Applicants respectfully submit the basis for the objections to claims 11 and 13 has been removed.

4. *Claim rejections under 35 U.S.C. §103*

The Examiner rejected claims 7-16 under 35 U.S.C. §103(a) as being unpatentable over Vallana et al., U.S. Pat. No. 5,387,247 ("Vallana"), in view of Luthra et al., U.S. Pat. No. 5,294,489 ("Luthra"). Applicants respectfully traverse this rejection.

As the Examiner will be aware, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. Moreover, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); M.P.E.P. § 2143.03.

With respect to alleged obviousness, there must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561 (Fed. Cir. 1986). In fact, the absence of a suggestion to combine is dispositive in an obviousness determination. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997). The mere fact that the prior art can be combined or modified does not make the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01. The consistent criterion for determining obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988); M.P.E.P. § 2142. A recent Federal Circuit case makes clear that, in an obviousness situation, the prior art must disclose each and every element of the claimed

invention, and that any motivation to combine or modify the prior art must be based upon a suggestion in the prior art. *In re Lee*, 61 U.S.P.Q.2d 143 (Fed. Cir. 2002). Conclusory statements regarding common knowledge and common sense are insufficient to support a finding of obviousness. *Id.* at 1434-35.

The present claims recite annular heart valve bodies defining a central orifice and comprising a first circumferential layer of pyrolytic carbon not including fiber, a second circumferential layer of pyrolytic carbon including fiber, and a third layer of pyrolytic carbon not including fiber.

Applicants submit, at minimum, this rejection fails to meet the second criterion for obviousness set forth above. Vallana teaches a heart valve (Fig. 9) comprising, an annular valve body wrapped by (i) a substrate, such as Dacron (polyester) or Teflon (polytetrafluoroethylene), (col. 2, lines 32-58), coated with (ii) turbostratic biocompatible carbon (Figs. 7-9, and col. 7, lines 11-23). Luthra teaches a reinforcement phase, such as cloth or carbon fiber (col. 3, lines 37-40), coated with, in order from the reinforcement phase outward (col. 4, lines 54-59), (a) an inner layer material, such as metal carbide, metal boride, or metal oxide (col. 2, line 63 to col. 3, line 6); (b) an interlayer material, such as carbon (col. 3, lines 12-21); and (c) an outer layer material, such as metal carbide, metal boride, rhodium, iridium, metal nitride, or metal silicide (col. 2, line 63 to col. 3, line 11). The Examiner also pointed to col. 12, lines 36-43, which teach a reinforcement phase comprising silicon carbide on a carbon core, coated with two layers of pyrolytic carbon and carbon-silicon. However, the only application of the teachings of Luthra to Vallana would be to coat Dacron or Teflon cloth with the (a)-(b)-(c) structure of Luthra, with subsequent wrapping of the cloth-(a)-(b)-(c) structure around an annular valve body.

The present claims, in contrast, refer to the annular valve body *itself* and the layers it comprises (also see p. 2, lines 22-25). What may be wrapped around the annular valve body is irrelevant.

Even if combined, Vallana and Luthra do not disclose all the limitations of the present claims. Therefore, this rejection is improper. Moreover, there is no suggestion to modify Vallana and Luthra to arrive at the present invention. Applicants respectfully submit that the Examiner's assertion that the pending claims are obvious in view of Vallana and Luthra is necessarily based on the improper use of hindsight, using the present disclosure as a guide.

Therefore, Applicants respectfully request this rejection of claims 7-16 be withdrawn.

5. *Conclusion*

Applicants submit claims 7-16 are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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